Diagnostic Adverse Event Report

Pharmacovigilance
United States Department of Agriculture
Center for Veterinary Biologics
510 South 17th Street, Suite 104
Ames, IA 50010
Phone: (515)232-5785 FAX: (515)232-7120

***Product information** (List ALL diagnostic products with problem)

*Brand Name or Generic Name	*Manufacturer or U.S. Vet. License	Serial (lot) Number**	Date of product use (mm/dd/yyyy)
1			
2			
3			
4			

**Prefer kit (box) Serial Number – if not available, include all component lot or serial numbers. If available, include shipping date.

***Problem description**

Briefly describe problem and provide information regarding the following questions:
Any component deviations (e.g. color, turbidity etc.)?
Current insert read and followed?
Deviations from insert directions?
Were components from different serials combined?
Were kit validation parameters met?

Reporter's information

This event has been reported to the manufacturer(s): No ☐ Yes ☐

Provide manufacturer case identification number (s), if available _____

Relationship to animal: ☐ Veterinarian/Veterinary Staff
☐ Diagnostic Lab Personnel
☐ Owner/Agent

*Reporter's first name:	*Reporter's last name:
*Reporter's phone number:	*Today's Date:

*Required information